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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 10 April 2000 (10.04.00)	
International application No. PCT/CA99/00695	**Applicant's or agent's file reference** T8463748WO
International filing date (day/month/year) 29 July 1999 (29.07.99)	**Priority date** (day/month/year) 31 July 1998 (31.07.98)
Applicant RICCI, Donald, R. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

29 February 2000 (29.02.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

RECEIVED
DEC 08 1999
GOWLING, STRATHY & HENDERSON
PATENT DEPARTMENT

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
GOWLING, STRATHY & HENDERSON
Attn. NASSIF, Omar A.
Suite 4900
Commerce Court West
Toronto, Ontario M5L 1J3
CANADA

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference T8463748WO	Date of mailing *(day/month/year)* 01/12/1999
International application No. PCT/CA 99/ 00695	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
Applicant NOVO RPS ULC et al.	International filing date *(day/month/year)* 29/07/1999

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed Instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Nuria Toribio Gonzalez

N[redacted] O FORM PCT/ISA/220 [redacted]

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pbulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the International application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

BNSDOCID: <XSISA220NOENP4_I_>

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

BNSDOCID: <XSISA220NOENP4_I_>

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
T8463748WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CA 99/ 00695	29/07/1999	31/07/1998
Applicant		
NOVO RPS ULC et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 11

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNAT[redacted]L SEARCH REPORT

International application No.
PCT/CA 99/ 00695

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 32-55
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv)- Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
CA 99/00695

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 749 825 A (FISCHELL ROBERT E ET AL) 12 May 1998 (1998-05-12) figure 3 column 2, line 60 -column 3, line 15	1,13
A	FR 2 740 346 A (DEBIOTECH SA) 30 April 1997 (1997-04-30) figures 1,4-6 page 3, line 24 -page 5, line 36 page 6, line 33 -page 7, line 5	1,13
A	FR 2 749 160 A (BERGERON PATRICE) 5 December 1997 (1997-12-05) figures 1,2 page 3, line 13 -page 5, line 12	1,13

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 November 1999	01/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCA 99/00695

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 14028 A (DIVYSIO SOLUTIONS LTD ;PENN IAN M (CA); RICCI DONALD R (CA)) 17 May 1996 (1996-05-17) figures 5-7 page 14, line 8 - line 23	1,13
A	US 5 669 924 A (SHAKNOVICH ALEXANDER) 23 September 1997 (1997-09-23) figures 1,3,9,10,13 figures 14A,B figures 15-17 column 11, line 10 -column 12, line 47 column 15, line 13 -column 16, line 16	1,13
A	EP 0 495 263 A (KENDALL & CO) 22 July 1992 (1992-07-22) figures 1D,2 column 3, line 16 - line 39 column 4, line 32 - line 44	1,13
A	WO 98 23319 A (PALESTRANT AUBREY M) 4 June 1998 (1998-06-04) figures 1,4 page 8, line 12 -page 9, line 26	1,13
A	US 4 134 402 A (MAHURKAR SAKHARAM D) 16 January 1979 (1979-01-16) figure 1 column 2, line 19 - line 56	1,13

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
/CA 99/00695

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5749825	A	12-05-1998	NONE		
FR 2740346	A	30-04-1997	AU	7499296 A	22-05-1997
			WO	9716217 A	09-05-1997
FR 2749160	A	05-12-1997	EP	0904032 A	31-03-1999
			WO	9745072 A	04-12-1997
WO 9614028	A	17-05-1996	CA	2134997 A	04-05-1996
			AT	166783 T	15-06-1998
			AU	3739795 A	31-05-1996
			CZ	9701329 A	17-12-1997
			DE	69502817 D	09-07-1998
			DE	69502817 T	25-02-1999
			EP	0751752 A	08-01-1997
			EP	0847734 A	17-06-1998
			ES	2119487 T	01-10-1998
			GR	3027774 T	30-11-1998
			HK	1009322 A	28-05-1999
			JP	10508234 T	18-08-1998
			US	5755771 A	26-05-1998
			US	5906640 A	25-05-1999
US 5669924	A	23-09-1997	AU	7472796 A	15-05-1997
			WO	9715346 A	01-05-1997
EP 0495263	A	22-07-1992	US	5167623 A	01-12-1992
			AU	647552 B	24-03-1994
			AU	8883491 A	02-07-1992
			CA	2056964 A	28-06-1992
			DE	69108219 D	20-04-1995
			DE	69108219 T	26-10-1995
			JP	4303457 A	27-10-1992
WO 9823319	A	04-06-1998	US	5807311 A	15-09-1998
US 4134402	A	16-01-1979	NONE		

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

NASSIF,Omar A.
Gowling Lafleur Henderson LLP
Suite 4900
Commerce Court West
Toronto, Ontario M5L 1J3
CANADA

RECEIVED
NOV 27 2000
GOWLING LAFLEUR HENDERSON LLP
PATENT DEPARTMENT

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	15.11.2000
Applicant's or agent's file reference T8463748WO	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/00695	29/07/1999	31/07/1998

Applicant
NOVO RPS ULC et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes. if any. is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Edel, M Tel.+49 89 2399-2426

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
T8463748WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/00695	29/07/1999	31/07/1998
International Patent Classification (IPC) or national classification and IPC A61F2/06		
Applicant NOVO RPS ULC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29/02/2000	15.11.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hooper, M Telephone No. +49 89 2399 7438

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00695

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-12 as originally filed

Claims, No.:

1-60 with telefax of 29/08/2000

Drawings, sheets:

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☒ the entire international application.

☐ claims Nos. .

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-31, 56-60 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 32-55.

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Re Item III

1. The search examiner found that no search was to be carried out for the subject-matter of claims 32-55, as they fall under the exclusions provided for in Rule 39.1(iv) PCT. The examining division agrees with the search examiner in this respect, as the independent claim 32 relates to a surgical method and contains the step of "navigating a first guidewire through the primary proximal body passageway" which can only be carried out by a skilled surgeon. This method is therefore a method for the treatment by surgery, for which no search-report needs to be established (Rule 39.1(iv) PCT) and no preliminary examination needs to be carried out (Rule 67.1(iv) PCT).

2. The subject-matter of claim 1 is to such a degree unclear, Article 6 PCT, that no meaningful opinion can be issued. The applicant intends to define the device claimed via a feature of its use, i. e. that "a guidewire is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire". This is not a device feature that clearly delineates the claimed subject-matter from the prior art, this being particularly important as this is the sole characterizing feature of the main claim. Furthermore, this feature is in contradiction to figures 5-7 and 11 & 12 of the application, which clearly show that both passageways have a guidewire disposed therein.

   As this feature renders the scope of the claimed subject-matter unclear, it is currently not possible to establish an opinion on novelty and inventive step. As all remaining claims are directly or indirectly dependent on claim 1 or claim 13, which contains the same clarity problem, the subject-matter of these claims is also affected and no opinion on novelty or inventive step can be issued.

   It is however to be pointed out to the applicant that the document US-A-5 749 825 appears to deprive claim 1 in the current form of novelty. When reading this document, esp. column 3, lines 32-48, it appears that the device has at one point one guidewire deployed in one of the tubular passageways, yet the other passageway is free of a guidewire.

Re Item VII

1. Claim 13 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT). Consequently, as claims 14-24 are copies of claims 2-12, the remainder of the claims should also be adapted.

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. It is a requirement of Rule 11.13(l) PCT that reference signs not mentioned in the description and claims shall not appear in the drawings and vice versa. This requirement is not met with respect to the reference sign "47" which appears in the drawings (Figures 4-6) but not in the description.

4. Some regional and national offices, e.g. the EPO, do not allow the incorporation by reference of other documents (be they published or not), as is done throughout the application. Should the application enter the regional phase before the EPO it will become necessary to replace such statements with the specific inclusion of the subject-matter of relevance to the application.

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
T8463748WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/00695	29/07/1999	31/07/1998
International Patent Classification (IPC) or national classification and IPC A61F2/06		
Applicant NOVO RPS ULC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29/02/2000	15.11.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hooper, M Telephone No. +49 89 2399 7438

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00695

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-12 as originally filed

Claims, No.:

1-60 with telefax of 29/08/2000

Drawings, sheets:

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: . which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description. pages:
- ☐ the claims. Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☒ the entire international application.

☐ claims Nos. .

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-31, 56-60 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 32-55.

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Re Item III

1. The search examiner found that no search was to be carried out for the subject-matter of claims 32-55, as they fall under the exclusions provided for in Rule 39.1(iv) PCT. The examining division agrees with the search examiner in this respect, as the independent claim 32 relates to a surgical method and contains the step of "navigating a first guidewire through the primary proximal body passageway" which can only be carried out by a skilled surgeon. This method is therefore a method for the treatment by surgery, for which no search-report needs to be established (Rule 39.1(iv) PCT) and no preliminary examination needs to be carried out (Rule 67.1(iv) PCT).

2. The subject-matter of claim 1 is to such a degree unclear, Article 6 PCT, that no meaningful opinion can be issued. The applicant intends to define the device claimed via a feature of its use, i. e. that "a guidewire is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire". This is not a device feature that clearly delineates the claimed subject-matter from the prior art, this being particularly important as this is the sole characterizing feature of the main claim. Furthermore, this feature is in contradiction to figures 5-7 and 11 & 12 of the application, which clearly show that both passageways have a guidewire disposed therein.

   As this feature renders the scope of the claimed subject-matter unclear, it is currently not possible to establish an opinion on novelty and inventive step. As all remaining claims are directly or indirectly dependent on claim 1 or claim 13, which contains the same clarity problem, the subject-matter of these claims is also affected and no opinion on novelty or inventive step can be issued.

   It is however to be pointed out to the applicant that the document US-A-5 749 825 appears to deprive claim 1 in the current form of novelty. When reading this document, esp. column 3, lines 32-48, it appears that the device has at one point one guidewire deployed in one of the tubular passageways, yet the other passageway is free of a guidewire.

Re Item VII

1. Claim 13 comprises all the features of claim 1 and is therefore not appropriately formulated as a claim dependent on the latter (Rule 6.4 PCT). Consequently, as claims 14-24 are copies of claims 2-12, the remainder of the claims should also be adapted.

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. It is a requirement of Rule 11.13(l) PCT that reference signs not mentioned in the description and claims shall not appear in the drawings and vice versa. This requirement is not met with respect to the reference sign "47" which appears in the drawings (Figures 4-6) but not in the description.

4. Some regional and national offices, e.g. the EPO, do not allow the incorporation by reference of other documents (be they published or not), as is done throughout the application. Should the application enter the regional phase before the EPO it will become necessary to replace such statements with the specific inclusion of the subject-matter of relevance to the application.

What is claimed is:

1. An endovascular sleeve for delivering a pair of guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end extending beyond the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway;

characterized in that a guidewire is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire.

2. The endovascular sleeve defined in claim 1, further comprising a radioopaque marker disposed thereon.

3. The endovascular sleeve defined in claim 2, wherein the radioopaque marker is disposed at the junction.

4. The endovascular sleeve defined in any one of claims 1-3, wherein the first passageway has a substantially circular cross-section.

5. The endovascular sleeve defined in any one of claims 1-3, wherein the second passageway has a substantially circular cross-section.

6. The endovascular sleeve defined in any one of claims 1-3, wherein both the first passageway and the second passageway have a substantially circular cross-section.

7. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end extends beyond the second distal end by a margin of at least about 0.3 cm.

8. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end extends beyond the second distal end by a margin in the range of from about 0.3 to about 3 cm.

9. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end extends beyond the second distal end by a margin in the range of from about 0.5 to about 2 cm.

10. The endovascular sleeve defined in any one of claims 1-9, wherein the first distal end is chamfered.

11. The endovascular sleeve defined in any one of claims 1-9, wherein the second distal end is chamfered.

12. The endovascular sleeve defined in any one of claims 1-9, wherein both the first distal end and the second distal end are chamfered.

13. An expansible prosthesis delivery system for delivery of an expansible prosthesis to a bifurcated body passageway, the system comprising:

a catheter;

a guidewire; and

an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end extending beyond the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway;

characterized in that the guidewire is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire.

14. The system defined in claim 13, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

15. The system defined in claim 14, wherein the radioopaque marker is disposed at the junction.

16. The system defined in any one of claims 13-15, wherein the first passageway has a substantially circular cross-section.

17. The system defined in any one of claims 13-15, wherein the second passageway has a substantially circular cross-section.

18. The system defined in any one of claims 13-15, wherein both the first passageway and the second passageway have a substantially circular cross-section.

19. The system defined in any one of claims 13-18, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

20. The system defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

21. The system defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

22. The system defined in any one of claims 13-21, wherein the first distal end is chamfered.

23. The system defined in any one of claims 13-21, wherein the second distal end is chamfered.

24. The system defined in any one of claims 13-21, wherein both the first distal end and the second distal end are chamfered.

25. The system defined in any one of claims 13-24, wherein the catheter comprises at least one expandable member.

26. The system defined in claim 25, wherein the expandable member is disposed adjacent a distal end of the catheter.

27. The system defined in any one of claims 25-26, wherein the catheter comprises two expandable members.

28. The system defined in any one of claims 25-27, wherein the catheter comprises a substantially Y-shaped expandable member.

29. The system defined in any one of claims 25-28, wherein the expandable member is a balloon.

30. The system defined in any one of claims 25-29, further comprising a bifurcated stent disposed on the expandable member.

31. The system defined in claim 30, wherein the bifurcated stent is mounted on the expandable member.

32. A method for delivery of a bifurcated stent to a target bifurcated body passageway having a proximal body passageway, a first distal body passageway and a second distal body passageway using an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway, the method comprising the steps of:

(i) navigating a first guidewire through the primary proximal body passageway and into the first distal body passageway;

(ii) feeding the first tubular passageway of the endovascular sleeve over the first guidewire;

(iii) navigating the endovascular sleeve through the primary proximal body passageway until the first distal end is disposed in the first distal body passageway and the junction abuts a crotch in the bifurcated body passageway;

(iv) navigating a second guidewire through the second tubular passageway and into the second distal body passageway;

(v) withdrawing the endovascular sleeve from the body passageway;

(vi) guiding a catheter over the first guidewire and the second guidewire, the catheter having a bifurcated stent disposed thereon;

(vii) navigating the bifurcated stent to the target bifurcated body passageway; and

(viii) expanding the bifurcated stent.

33. The method defined in claim 32, wherein the catheter further comprises at least one expandable member on which the bifurcated stent is disposed and Step (viii) comprises expanding the expandable member to convey a radially expansive force to the bifurcated stent.

34. The method defined in claim 33, wherein the expandable member is disposed adjacent a distal end of the catheter.

35. The method defined in any one of claims 33-34, wherein the catheter comprises two expandable members.

36. The method defined in any one of claims 33-35, wherein the catheter comprises a substantially Y-shaped expandable member.

37. The method defined in any one of claims 33-36, wherein the expandable member is a balloon.

38. The method defined in any one of claims 32-37, wherein the bifurcated

stent is constructed of a plastically deformable material.

39. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of stainless steel.

40. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of a self-expanding material.

41. The method defined in any one of claims 32-40, wherein the catheter further comprises a sheath covering the bifurcated stent and Step (viii) comprises removing the sheath to expose the bifurcated stent resulting in a radially expansive force thereon.

42. The method defined in claim 40, wherein the self-expanding material is nitinol.

43. The method defined in any one of claims 40 and 42, wherein the self-expanding material expands at a temperature of greater than about 30°C.

44. The method defined in any one of claims 40-42, wherein the self-expanding material expands at a temperature of in the range of from about 30° to about 40°C.

45. The method defined in any one of claims 32-44, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

46. The method defined in claim 45, wherein the radioopaque marker is disposed at the junction.

47. The method defined in any one of claims 32-46, wherein the first passageway has a substantially circular cross-section.

48. The method defined in any one of claims 32-46, wherein the second passageway has a substantially circular cross-section.

49. The method defined in any one of claims 32-46, wherein both the first passageway and the second passageway have a substantially circular cross-section.

50. The method defined in any one of claims 32-49, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

51. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

52. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

53. The method defined in any one of claims 32-52, wherein the first distal end is chamfered.

54. The method defined in any one of claims 32-52, wherein the second distal end is chamfered.

55. The method defined in any one of claims 32-52, wherein the both the first distal end and the second distal end are chamfered.

56. The endovascular sleeve defined in any one of claims 1-12, wherein the second proximal end extends beyond the first proximal end.

57. The endovascular sleeve defined in claim 56, wherein the first tubular passageway has a length such that the first proximal end does not emanate from

a subject and the second tubular passageway has a length such that the second proximal emanates from the subject.

58. The endovascular sleeve defined in any one of claims 1-12, wherein the second proximal end the first proximal end and the second proximal end are substantially juxtaposed.

59. The endovascular sleeve defined in claim 58, wherein the first tubular passageway and the second tubular passageway have a length such that the first proximal end and the second proximal end each emanate from a subject.

60. The endovascular sleeve defined in any one of claims 1-12 and 56-59, wherein the first tubular passageway and the second tubular passageway are each constructed of a material having sufficient integrity to be navigated through tortuous body passageways.

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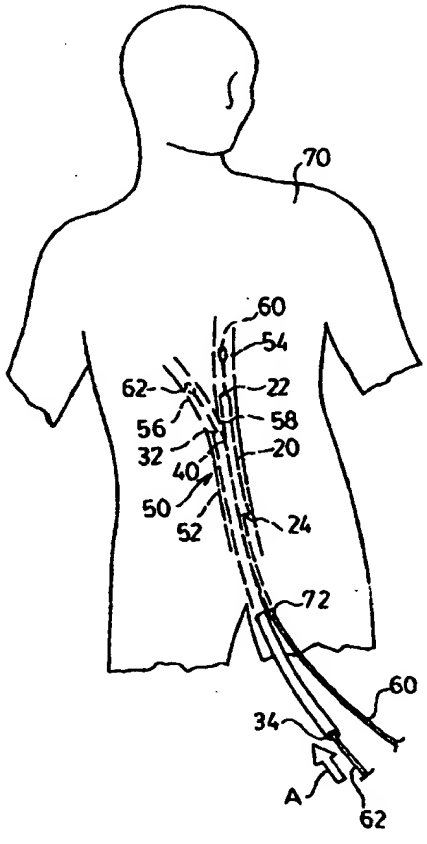
Published
With international search report.

(54) Title: BIFURCATED STENT DELIVERY SYSTEM AND METHOD OF USE

(57) Abstract

An endovascular sleeve which can be utilized to navigate a pair of guidewires to a bifurcated body passageway such that, once in place, the guidewires are substantially untwisted or untangled. This greatly facilitates delivery of the bifurcated stent to the bifurcated artery.



BIFURCATED STENT DELIVERY SYSTEM AND METHOD OF USE

TECHNICAL FIELD

In one of its aspects, the present invention relates to an endovascular sleeve for use in delivery of a bifurcated stent. In another of its aspects, the present invention relates to bifurcated stent delivery kit. In yet another of its aspects, the present invention relates to a method for delivery of a bifurcated stent.

BACKGROUND ART

Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expansible prosthesis". As used throughout this specification, the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g., a lumen or artery).

In the past ten years, the use of stents has attracted an increasing amount of attention due the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g., natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

Stent development has evolved to the point where the vast majority of currently available stents rely on controlled plastic deformation of the entire structure of the stent at the target body passageway so that only sufficient force to maintain the patency of the body passageway is applied during expansion of the stent.

Generally, in many of these systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (for example, for intravascular implantation

the target area of the vessel can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is expanded thereby plastically deforming the entire structure of the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to expand the stent (i.e., the applied the force exceeds the minimum force above which the stent material will undergo plastic deformation) while maintaining the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and is subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

See, for example, any of the following patents:

United States patent 4,733,665 (Palmaz),
United States patent 4,739,762 (Palmaz),
United States patent 4,800,882 (Gianturco),
United States patent 4,907,336 (Gianturco),
United States patent 5,035,706 (Gianturco et al.),
United States patent 5,037,392 (Hillstead),
United States patent 5,041,126 (Gianturco),
United States patent 5,102,417 (Palmaz),
United States patent 5,147,385 (Beck et al.),
United States patent 5,282,824 (Gianturco),
United States patent 5,316,023 (Palmaz et al.),
Canadian patent 1,239,755 (Wallsten),
Canadian patent 1,245,527 (Gianturco et al.),
Canadian patent application number 2,171,047 (Penn et al.),
Canadian patent application number 2,175,722 (Penn et al.),
Canadian patent application number 2,185,740 (Penn et al.),
Canadian patent application number 2,192,520 (Penn et al.),
International patent application PCT/CA97/00151 (Penn et al.), and
International patent application PCT/CA97/00152 (Penn et al.),

the contents of each of which are hereby incorporated by reference, for a discussion on previous stent designs and deployment systems.

All of the stents described in the above-identified patents share the common design of being mono-tubular and thus, are best suited to be delivered and implanted in-line in the body passageway. These known stents are inappropriate for use in a bifurcated body passageway (e.g., a body passageway comprising a parent passageway that splits into a pair of passageways). Further, these stents are inappropriate for use in a body passageway having side branches since: (i) inaccurate placement of the stent substantially increases the risk to the patient, (ii) the risk of passageway closure in the side branches is increased, and (iii) the side branches will be substantially inaccessible.

Indeed, the Physician Guide published in support of the Palmaz-Schatz stent states on page 32 (the contents of which are hereby incorporated by reference):

> " ... no attempt should be made following placement of a PALMAZ-SCHATZ stent to access the side branch with a guide wire or a balloon, as such attempts may result in additional damage to the target vessel or the stent. Attempts to treat obstructed side branches within stented segments can result in balloon entrapment, necessitating emergency bypass surgery."

Thus, when installed, the Palmaz-Schatz stent admittedly shields side branches emanating from the target area of the body passageway effectively permanently. This can be problematic since the only way to treat blockage or other problems associated with the side branches is to perform the type of surgery which installation of the stent was intended to avoid.

This contraindication for conventional mono-tubular stents is corroborated by a number of investigators. See, for example, the following:

1. *Interventional Cardiovascular Medicine: Principles and Practice* (1994); Publisher: Churchill Livingstone Inc.;

pages 221-223 (Ohman et al.), 487-488 (Labinaz et al.), 667-668 (Bashore et al.) and 897 (Bailey et al.), including references cited therein;

2. Gianturco-Roubin Flex-Stent™ Coronary Stent: Physician's Guide; page 2, Paragraph 3 under WARNINGS;

3. *Circulation*, Vol. 83, No. 1, January 1991 (Schatz et al.); entitled "Clinical Experience With the Palmaz-Schatz Coronary Stent"; pages 148-161 at page 149; and

4. *American Heart Journal*, Vol. 127, No. 2, February 1994 (Eeckhout et al.); entitled "Complications and follow-up after intracoronary stenting: Critical analysis of a 6-year single-center experience"; pages 262-272 at page 263,

the contents of each of which are hereby incorporated by reference.

Further, some investigators have attempted to install individual stents in each branch of the bifurcated body passageway. However, this approach is fraught with at least two significant problems. First, implantation of three individual stents is technically challenging and, together with the expansive forces generated upon implantation, results in subjecting the central walls of the bifurcated body passageway to undue stress and trauma which may lead to post-procedural complications. Second, since the central walls (i.e., in the crotch area) of the bifurcated body passageway are not supported by the individual stents, this area of the passageway is left substantially unprotected and susceptible to blockage.

One particular problem area with bifurcated body passageways is the occurrence of bifurcation lesions within the coronary circulation. Generally, these legions may be classified as follows:

Type	Characteristic
A	Prebranch stenosis not involving the ostium of the side branch;
B	Postbranch stenosis of the parent vessel not involving the origin of the side branch;
C	Stenosis encompassing the side branch but not involving the ostium;
D	Stenosis involving the parent vessel and ostium of the side branch;
E	Stenosis involving the ostium of the side branch only; and
F	Stenosis discretely involving the parent vessel and ostium of the side branch.

See *Atlas of Interventional Cardiology* (Popma et al.), 1994, pages 77-79, the contents of which are hereby incorporated by reference. The presence of bifurcation lesions is predictive of increased procedural complications including acute vessel closure.

United States patent 4,994,071 (MacGregor), the contents of which are hereby incorporated by reference, discloses a bifurcating stent apparatus. The particular design incorporates a series of generally parallel oriented loops interconnected by a sequence of "half-birch" connections. The lattice structure of the illustrated stent is constructed of wire. The use of such wire is important to obtain the loop structure of the illustrated design. United States patents 3,993,078 (Bergentz et al.) and 5,342,387 (Summers), the contents of each of

which are hereby incorporated by reference, also disclose and illustrate a bifurcated stent design constructed of wire.

In published Canadian patent application number 2,134,997 (Penn et al.) and published International patent application PCT/CA97/00294 (Penn et al.), the contents of each of which are hereby incorporated by reference, we describe various novel bifurcated stents.

Thus, while bifurcated stents are generally known, the base of knowledge relating thereto is significantly less than that relating to monotubular stents. Not surprisingly there is a similar imbalance of knowledge relating to the delivery systems for such stents. Specifically, there is vast knowledge relating delivery systems for monotubular stents compared to the knowledge that exists for bifurcated stent delivery systems.

In the delivery of any stent (monotubular or bifurcated) it is reasonably well accepted that the stent is mounted on a catheter which is navigated over a guidewire previously inserted through a guide catheter to the target location. Thus, when the object is to deliver a bifurcated stent, it is envisaged that a pair of guidewires would be used - i.e., one for each of the two passageways that branch off the primary passageway. As such, it is important that, in the primary passage, the guidewires do not become entangled, either in the guide catheter or the body passageway, as this will prevent navigation of the catheter to the target location. In addition, the limited size of the guide catheter determines the bulkiness of the bifurcated stent delivery system. The practical result of this is that the current approach of delivering bifurcated stents is bulky, cumbersome and technically challenging. To date, the present inventors are unaware of a solution to the problems of conventional bifurcated stent delivery.

Accordingly, it would be desirable to have a system which could be used to navigate a pair of guidewires in a substantially untangled manner to facilitate delivery of the bifurcated stent. It would be further advantageous is such a system were relatively miniaturized compared to conventional bifurcated stent delivery systems.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a novel bifurcated stent delivery system which obviates or mitigates at least one of the above-mentioned disadvantages of the prior art.

Thus, in one of its aspects, the present invention provides an endovascular sleeve for delivering a pair of guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

A bifurcated stent delivery kit for delivery of a bifurcated stent to a bifurcated body passageway, the kit comprising:

a catheter;

a pair of guidewires; and

an endovascular sleeve for delivering the guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

In yet another of its aspects, the present invention provides method for delivery of a bifurcated stent to a target bifurcated body passageway having a proximal body passageway, a first distal body passageway and a second distal body passageway using an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define

a junction which abuts against a crotch in the bifurcated body passageway, the method comprising the steps of:

(i) navigating a first guidewire through the primary proximal body passageway and into the first distal body passageway;

(ii) feeding the first tubular passageway of the endovascular sleeve over the first guidewire;

(iii) navigating the endovascular sleeve through the primary proximal body passageway until the first distal end is disposed in the first distal body passageway and the junction abuts a crotch in the bifurcated body passageway;

(iv) navigating a second guidewire through the second tubular passageway and into the second distal body passageway;

(v) withdrawing the endovascular sleeve from the body passageway;

(vi) guiding a catheter over the first guidewire and the second guidewire, the catheter having a bifurcated stent disposed thereon;

(vii) navigating the bifurcated stent to the target bifurcated body passageway; and

(viii) expanding the bifurcated stent.

Thus, the present inventors have developed an endovascular sleeve which can be utilized to navigate a pair of guidewires to a bifurcated body passageway such that, once in place, the guidewires are substantially untwisted or untangle. This greatly facilitates delivery of the bifurcated stent to the bifurcated artery.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in which:

Figure 1 illustrates a side elevation of a first embodiment of the present endovascular sleeve;

Figure 2 illustrates a side elevation of a second embodiment of the present endovascular sleeve;

Figures 3-7 illustrate enlarged views of how the present endovascular sleeve may be used to deliver a pair of guidewires;

Figures 8-12 illustrate perspective views of how the present endovascular sleeve may be used to deliver a pair of guidewires;

Figures 13-15 illustrate enlarged view of how a bifurcated stent may be delivered once the pair of guidewires are in place; and

Figure 16 illustrates an enlarged view of the implanted bifurcated stent delivered in Figures 13-15.

BEST MODE FOR CARRYING OUT THE INVENTION

With reference to Figure 1, there is shown an endovascular sleeve 10. Endovascular sleeve 10 comprises a first tubular passageway 20 having a first distal end 22 and first proximal end 24. Endovascular sleeve 10 further comprises a second tubular passageway 30 having a second distal end 32 and second proximal end 34. First tubular passageway 20 and second tubular passageway 30 are joined and fixed with respect to one another along a seam 40. As illustrated, first distal end 22 extends beyond second distal end 32. This offset between first distal end 22 and second distal end 32 defines a junction 45 Preferably, first distal end 22 extends beyond second distal end 32 by a margin of at least about 0.3 cm, more preferably by a margin in the range of from about 0.3 cm to about 3 cm, most preferably by a margin in the range of from about 0.5 cm to about 2 cm. Further, first proximal end 24 is significantly offset with respect to second proximal end 34. As will be developed below, this offset renders endovascular sleeve 10 as a "over-the-wire/monorail" delivery system. As shown, each of first distal end 22 and second distal end 32 are chamfered or bevelled.

With reference to Figure 2, there is shown an endovascular sleeve 100. Endovascular sleeve 100 comprises a first tubular passageway 120 having a first distal end 122 and first proximal end 124. Endovascular sleeve 100 further comprises a second tubular passageway 130 having a second distal end 132 and second proximal end 134. First tubular passageway 120 and second tubular passageway 130 are joined and fixed with respect to one another along a seam 140. As illustrated, first distal end 122 extends beyond second distal end 132. This offset between first distal end 122 and second distal end 132 defines a

junction 145. Preferably, first distal end 122 extends beyond second distal end 132 by a margin of at least about 0.3 cm, more preferably by a margin in the range of from about 0.3 cm to about 3 cm, most preferably by a margin in the range of from about 0.5 cm to about 2 cm. Further, unlike in the "over-the-wire/monorail" delivery system illustrated in Figure 1, first proximal end 124 is substantially even with respect to second proximal end 134. This relatively even disposition of first proximal end 124 and second proximal end 134 renders endovascular sleeve 100 as a "double over-the-wire" delivery system. As shown, each of first distal end 122 and second distal end 132 are chamfered or bevelled.

The material used to constructed endovascular sleeve 10 is not particularly restricted provided of course that it: (i) sufficient integrity to by navigated through tortuous body passageways, and (ii) is non-toxic to the subject in which endovascular sleeve 10 is being navigated. Non-limiting examples of suitable materials include bioplastic polymers, a flexible metal tube and the like.

With reference to Figures 3-7, the use of endovascular sleeve 10 used to deliver a pair of guidewires will be discussed.

As shown, a bifurcated body passageway 50 comprises a proximal passageway 52 and a pair of distal passageways 54,56. The junction of distal passageways 54,56 defines a crotch 58. For clarity, the stenosis of bifurcated body passageway 50 is not illustrated.

With reference to Figure 3, a first guidewire 60 is navigated through proximal passageway 52 and into distal passageway 54 in the direction of arrow A.

With reference to Figure 4, first tubular passageway 20 is fed over guidewire 60 in the direction of arrow A and navigated until it enters distal passageway 54 and junction 40 of endovascular sleeve 10 abuts crotch 58 of bifurcated body passageway 50. In the illustrated embodiment, endovascular sleeve 10 is provided with a radioopaque marker (e.g., made of gold and the like) near or at junction 40 so that the position of junction 40 relative to crotch 58 can be monitored using conventional image radiography techniques. Once endovascular sleeve 10 is positioned in this fashion, second distal end 32 of second tubular passageway 30 opens into distal passageway 56.

With reference to Figure 5, once endovascular sleeve 10 is in place (i.e., as shown in Figure 4), a second guidewire 62 is fed through second tubular passageway 30 into distal passageway 56 in the direction of arrow A.

With reference to Figure 6, once guidewires 60,62 are positioned correctly, endovascular sleeve 10 is withdrawn from bifurcated body passageway 50 in the direction of arrow B. As will be apparent to those of skill in the art, care should be taken to avoid twisting of endovascular sleeve 10 since this could result in conveyance of the twist to guidewires 60,62.

With reference to Figure 7, once endovascular sleeve 10 is completely withdrawn from bifurcated body passageway 50, guidewires 60,62 remain with the distal ends thereof in distal passageways 54,56, respectively.

With reference to Figures 8-12, there are illustrated perspective views of the use of endovascular sleeve 10 to deliver a pair of guidewires as described hereinabove with respect to Figures 3-7.

As illustrated, endovascular sleeve 10 is introduced to a subject 70 via a suitable incision near the groin of subject 70. Generally speaking, the concordance of the perspectives view illustrated in Figures 8-12 to the enlarged view illustrated in Figures 3-7 is as follows:

Figure 8 concords with Figure 3;
Figures 9 and 10 concord with Figure 4;
Figure 11 concords with Figure 5; and
Figure 12 concords with Figures 6 and 7.

As discussed above, endovascular sleeve 10 may be regarded as an "over-the-wire/monorail" delivery system. By this it is meant that, once the sleeve is in the correct position, one tubular passageway (30) remains over a guidewire (62) such that the proximal end thereof (34) emanates from the subject whereas the proximal end (24) of the other tubular passageway (20) does not emanate from the subject. In other words, the section of the other tubular passageway (20) between the bifurcated body passageway (50) and incision (72) in the subject (70) does not completely cover the other guidewire (60).

As discussed above, endovascular sleeve 100 may be regarded as a "double over-the-wire" delivery system. By this is meant that, once the sleeve is in the correct position, both tubular passage ways (120,130) remain over their respective guidewires (60,62) such that the proximal end (24) of each tubular passageway (120,130) emanates from the subject. In other words, both guidewires (60,62) are substantially completely covered by endovascular sleeve 100.

With reference to Figure 7, once the endovascular sleeve is removed, guidewires 60,62 remain as illustrated and are substantially untwisted to the point at which they emanate from the subject. With reference to Figure 13, at this point, a catheter 80 is used to deliver a bifurcated stent to bifurcated body passageway 50. Specifically, catheter 80 comprises a balloon 82 having a pair of tubes 84,86 emanating from one end thereof. Mounted on balloon 82 is a bifurcated stent 88. Tubes 84,86 are of a conventional, annular design such that they can be disposed over their respective guidewires and can receive a fluid which is used to fill balloon 82 resulting in expansion thereof. Thus, catheter 80 is navigated over guidewires 60,62 until the bifurcated stent is in the correct position - see Figure 14. At this point, a pressurized fluid (e.g., saline) is introduced into balloon 82 via tubes 84,86 resulting in expansion of balloon 82 and stent 88 - see Figure 15. Thereafter, balloon 82 is deflated conventionally and withdrawn from bifurcated body passage way 50 leaving stent 88 in a deployed state - see Figure 16. While balloon 82 is shown as a pair of adjacent single balloons, those of skill in the art will appreciate that a bifurcated balloon could be used in place of a pair of single balloons.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiments, as well as other embodiments of the invention , will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

What is claimed is:

1. An endovascular sleeve for delivering a pair of guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end (being longer than) the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

2. The endovascular sleeve defined in claim 1, further comprising a radioopaque marker disposed thereon.

3. The endovascular sleeve defined in claim 2, wherein the radioopaque marker is disposed at the junction.

4. The endovascular sleeve defined in any one of claims 1-3, wherein the first passageway has a substantially circular cross-section.

5. The endovascular sleeve defined in any one of claims 1-3, wherein the second passageway has a substantially circular cross-section.

6. The endovascular sleeve defined in any one of claims 1-3, wherein both the first passageway and the second passageway have a substantially circular cross-section.

7. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end is at least about 0.3 cm shorter than the second distal end.

8. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

9. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

10. The endovascular sleeve defined in any one of claims 1-9, wherein the first distal end is chamfered.

11. The endovascular sleeve defined in any one of claims 1-9, wherein the second distal end is chamfered.

12. The endovascular sleeve defined in any one of claims 1-9, wherein both the first distal end and the second distal end are chamfered.

13. A bifurcated stent delivery kit for delivery of a bifurcated stent to a bifurcated body passageway, the kit comprising:

a catheter;

a pair of guidewires; and

an endovascular sleeve for delivering the guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

14. The kit defined in claim 13, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

15. The kit defined in claim 14, wherein the radioopaque marker is disposed at the junction.

16. The kit defined in any one of claims 13-15, wherein the first passageway has a substantially circular cross-section.

17. The kit defined in any one of claims 13-15, wherein the second passageway has a substantially circular cross-section.

18. The kit defined in any one of claims 13-15, wherein both the first passageway and the second passageway have a substantially circular cross-section.

19. The kit defined in any one of claims 13-18, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

20. The kit defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

21. The kit defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

22. The kit defined in any one of claims 13-21, wherein the first distal end is chamfered.

23. The kit defined in any one of claims 13-21, wherein the second distal end is chamfered.

24. The kit defined in any one of claims 13-21, wherein both the first distal end and the second distal end are chamfered.

25. The kit defined in any one of claims 13-24, wherein the catheter comprises at least one expandable member.

26. The kit defined in claim 25, wherein the expandable member is disposed adjacent a distal end of the catheter.

27. The kit defined in any one of claims 25-26, wherein the catheter comprises two expandable members.

28. The kit defined in any one of claims 25-27, wherein the catheter comprises a substantially Y-shaped expandable member.

29. The kit defined in any one of claims 25-28, wherein the expandable member is a balloon.

30. The kit defined in any one of claims 25-29, further comprising a bifurcated stent disposed on the expandable member.

31. The kit defined in claim 30, wherein the bifurcated stent is mounted on the expandable member.

32. A method for delivery of a bifurcated stent to a target bifurcated body passageway having a proximal body passageway, a first distal body passageway and a second distal body passageway using an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway, the method comprising the steps of:

(i) navigating a first guidewire through the primary proximal body passageway and into the first distal body passageway;

(ii) feeding the first tubular passageway of the endovascular sleeve over the first guidewire;

(iii) navigating the endovascular sleeve through the primary proximal body passageway until the first distal end is disposed in the first distal body passageway and the junction abuts a crotch in the bifurcated body passageway;

(iv) navigating a second guidewire through the second tubular passageway and into the second distal body passageway;

(v) withdrawing the endovascular sleeve from the body passageway;

(vi) guiding a catheter over the first guidewire and the second guidewire, the catheter having a bifurcated stent disposed thereon;

(vii) navigating the bifurcated stent to the target bifurcated body passageway; and

(viii) expanding the bifurcated stent.

33. The method defined in claim 32, wherein the catheter further comprises at least one expandable member on which the bifurcated stent is disposed and Step (viii) comprises expanding the expandable member to convey a radially expansive force to the bifurcated stent.

34. The method defined in claim 33, wherein the expandable member is disposed adjacent a distal end of the catheter.

35. The method defined in any one of claims 33-34, wherein the catheter comprises two expandable members.

36. The method defined in any one of claims 33-35, wherein the catheter comprises a substantially Y-shaped expandable member.

37. The method defined in any one of claims 33-36, wherein the expandable member is a balloon.

38. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of a plastically deformable material.

39. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of stainless steel.

40. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of a self-expanding material.

41. The method defined in any one of claims 32-40, wherein the catheter further comprises a sheath covering the bifurcated stent and Step (viii) comprises removing the sheath to expose the bifurcated stent resulting in a radially expansive force thereon.

42. The method defined in claim 40, wherein the self-expanding material is nitinol.

43. The method defined in any one of claims 40 and 42, wherein the self-expanding material expands at a temperature of greater than about 30°C.

44. The method defined in any one of claims 40-42, wherein the self-expanding material expands at a temperature of in the range of from about 30° to about 40°C.

45. The method defined in any one of claims 32-44, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

46. The method defined in claim 45, wherein the radioopaque marker is disposed at the junction.

47. The method defined in any one of claims 32-46, wherein the first passageway has a substantially circular cross-section.

48. The method defined in any one of claims 32-46, wherein the second passageway has a substantially circular cross-section.

49. The method defined in any one of claims 32-46, wherein both the first passageway and the second passageway have a substantially circular cross-section.

50. The method defined in any one of claims 32-49, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

51. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

52. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

53. The method defined in any one of claims 32-52, wherein the first distal end is chamfered.

54. The method defined in any one of claims 32-52, wherein the second distal end is chamfered.

55. The method defined in any one of claims 32-52, wherein both the first distal end and the second distal end are chamfered.

What is claimed is:

1. An endovascular sleeve for delivering a pair of guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

2. The endovascular sleeve defined in claim 1, further comprising a radioopaque marker disposed thereon.

3. The endovascular sleeve defined in claim 2, wherein the radioopaque marker is disposed at the junction.

4. The endovascular sleeve defined in any one of claims 1-3, wherein the first passageway has a substantially circular cross-section.

5. The endovascular sleeve defined in any one of claims 1-3, wherein the second passageway has a substantially circular cross-section.

6. The endovascular sleeve defined in any one of claims 1-3, wherein both the first passageway and the second passageway have a substantially circular cross-section.

7. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end is at least about 0.3 cm shorter than the second distal end.

8. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

9. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

10. The endovascular sleeve defined in any one of claims 1-9, wherein the first distal end is chamfered.

11. The endovascular sleeve defined in any one of claims 1-9, wherein the second distal end is chamfered.

12. The endovascular sleeve defined in any one of claims 1-9, wherein both the first distal end and the second distal end are chamfered.

13. A bifurcated stent delivery kit for delivery of a bifurcated stent to a bifurcated body passageway, the kit comprising:

a catheter;

a pair of guidewires; and

an endovascular sleeve for delivering the guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

14. The kit defined in claim 13, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

15. The kit defined in claim 14, wherein the radioopaque marker is disposed at the junction.

16. The kit defined in any one of claims 13-15, wherein the first passageway has a substantially circular cross-section.

17. The kit defined in any one of claims 13-15, wherein the second passageway has a substantially circular cross-section.

18. The kit defined in any one of claims 13-15, wherein both the first passageway and the second passageway have a substantially circular cross-section.

19. The kit defined in any one of claims 13-18, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

20. The kit defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

21. The kit defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

22. The kit defined in any one of claims 13-21, wherein the first distal end is chamfered.

23. The kit defined in any one of claims 13-21, wherein the second distal end is chamfered.

24. The kit defined in any one of claims 13-21, wherein both the first distal end and the second distal end are chamfered.

25. The kit defined in any one of claims 13-24, wherein the catheter comprises at least one expandable member.

26. The kit defined in claim 25, wherein the expandable member is disposed adjacent a distal end of the catheter.

27. The kit defined in any one of claims 25-26, wherein the catheter comprises two expandable members.

28. The kit defined in any one of claims 25-27, wherein the catheter comprises a substantially Y-shaped expandable member.

29. The kit defined in any one of claims 25-28, wherein the expandable member is a balloon.

30. The kit defined in any one of claims 25-29, further comprising a bifurcated stent disposed on the expandable member.

31. The kit defined in claim 30, wherein the bifurcated stent is mounted on the expandable member.

32. A method for delivery of a bifurcated stent to a target bifurcated body passageway having a proximal body passageway, a first distal body passageway and a second distal body passageway using an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway, the method comprising the steps of:

(i) navigating a first guidewire through the primary proximal body passageway and into the first distal body passageway;

(ii) feeding the first tubular passageway of the endovascular sleeve over the first guidewire;

(iii) navigating the endovascular sleeve through the primary proximal body passageway until the first distal end is disposed in the first distal body passageway and the junction abuts a crotch in the bifurcated body passageway;

(iv) navigating a second guidewire through the second tubular passageway and into the second distal body passageway;

(v) withdrawing the endovascular sleeve from the body passageway;

(vi) guiding a catheter over the first guidewire and the second guidewire, the catheter having a bifurcated stent disposed thereon;

(vii) navigating the bifurcated stent to the target bifurcated body passageway; and

(viii) expanding the bifurcated stent.

33. The method defined in claim 32, wherein the catheter further comprises at least one expandable member on which the bifurcated stent is disposed and Step (viii) comprises expanding the expandable member to convey a radially expansive force to the bifurcated stent.

34. The method defined in claim 33, wherein the expandable member is disposed adjacent a distal end of the catheter.

35. The method defined in any one of claims 33-34, wherein the catheter comprises two expandable members.

36. The method defined in any one of claims 33-35, wherein the catheter comprises a substantially Y-shaped expandable member.

37. The method defined in any one of claims 33-36, wherein the expandable member is a balloon.

38. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of a plastically deformable material.

39. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of stainless steel.

40. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of a self-expanding material.

41. The method defined in any one of claims 32-40, wherein the catheter further comprises a sheath covering the bifurcated stent and Step (viii) comprises removing the sheath to expose the bifurcated stent resulting in a radially expansive force thereon.

42. The method defined in claim 40, wherein the self-expanding material is nitinol.

43. The method defined in any one of claims 40 and 42, wherein the self-expanding material expands at a temperature of greater than about 30°C.

44. The method defined in any one of claims 40-42, wherein the self-expanding material expands at a temperature of in the range of from about 30° to about 40°C.

45. The method defined in any one of claims 32-44, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

46. The method defined in claim 45, wherein the radioopaque marker is disposed at the junction.

47. The method defined in any one of claims 32-46, wherein the first passageway has a substantially circular cross-section.

48. The method defined in any one of claims 32-46, wherein the second passageway has a substantially circular cross-section.

49. The method defined in any one of claims 32-46, wherein both the first passageway and the second passageway have a substantially circular cross-section.

50. The method defined in any one of claims 32-49, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

51. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

52. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

53. The method defined in any one of claims 32-52, wherein the first distal end is chamfered.

54. The method defined in any one of claims 32-52, wherein the second distal end is chamfered.

55. The method defined in any one of claims 32-52, wherein both the first distal end and the second distal end are chamfered.

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 749 825 A (FISCHELL ROBERT E ET AL) 12 May 1998 (1998-05-12) figure 3 column 2, line 60 -column 3, line 15 ---	1,13
A	FR 2 740 346 A (DEBIOTECH SA) 30 April 1997 (1997-04-30) figures 1,4-6 page 3, line 24 -page 5, line 36 page 6, line 33 -page 7, line 5 ---	1,13
A	FR 2 749 160 A (BERGERON PATRICE) 5 December 1997 (1997-12-05) figures 1,2 page 3, line 13 -page 5, line 12 --- -/--	1,13

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 November 1999	01/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTER ONAL SEARCH REPORT

ational Application No
PCT/CA 99/00695

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropnate, of the relevant passages	Relevant to claim No.
A	WO 96 14028 A (DIVYSIO SOLUTIONS LTD ;PENN IAN M (CA); RICCI DONALD R (CA)) 17 May 1996 (1996-05-17) figures 5-7 page 14, line 8 - line 23	1,13
A	US 5 669 924 A (SHAKNOVICH ALEXANDER) 23 September 1997 (1997-09-23) figures 1,3,9,10,13 figures 14A,B figures 15-17 column 11, line 10 -column 12, line 47 column 15, line 13 -column 16, line 16	1,13
A	EP 0 495 263 A (KENDALL & CO) 22 July 1992 (1992-07-22) figures 1D,2 column 3, line 16 - line 39 column 4, line 32 - line 44	1,13
A	WO 98 23319 A (PALESTRANT AUBREY M) 4 June 1998 (1998-06-04) figures 1,4 page 8, line 12 -page 9, line 26	1,13
A	US 4 134 402 A (MAHURKAR SAKHARAM D) 16 January 1979 (1979-01-16) figure 1 column 2, line 19 - line 56	1,13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 99/00695

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 32-55
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv)- Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 99/00695

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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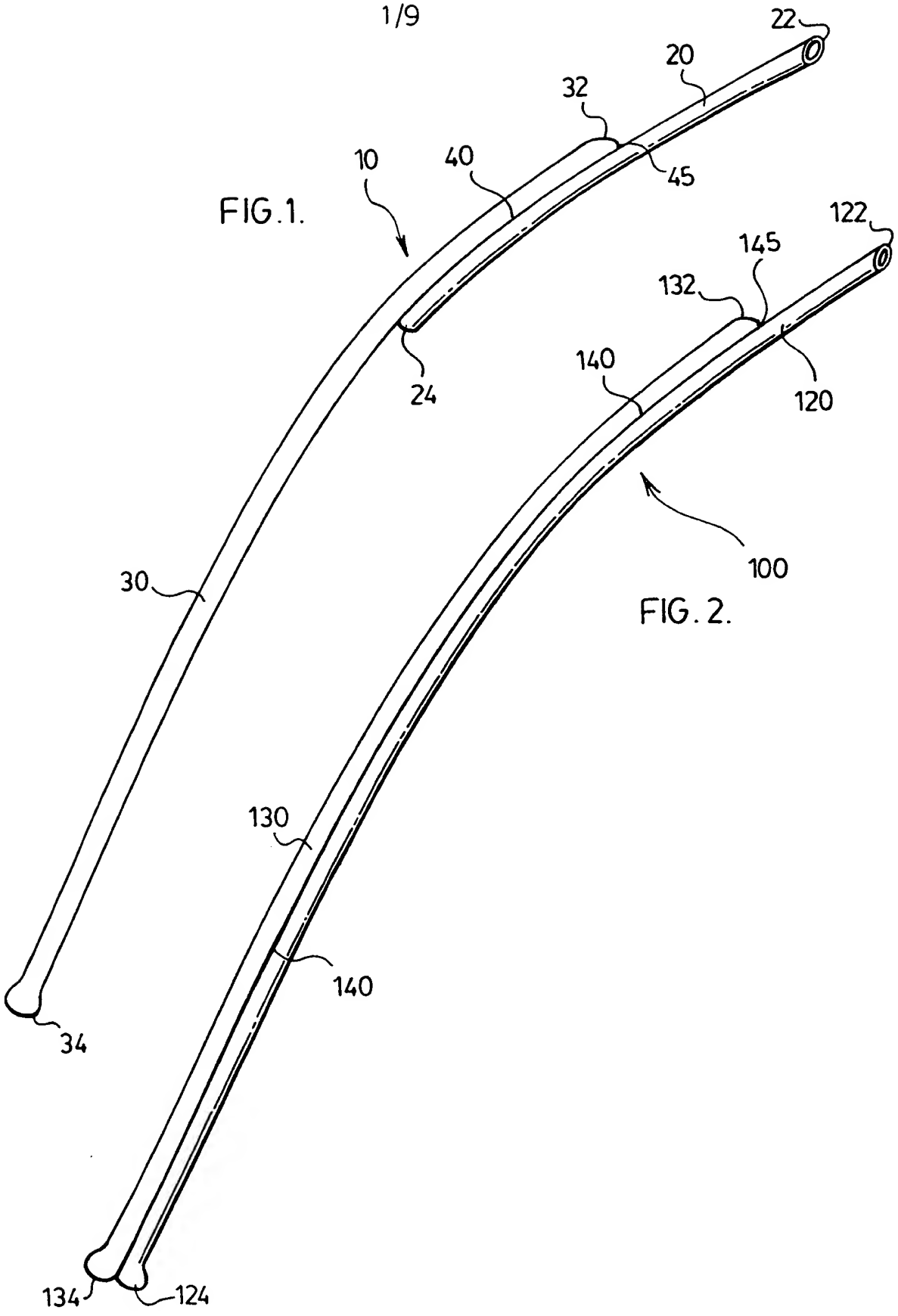

FIG. 1.

FIG. 2.

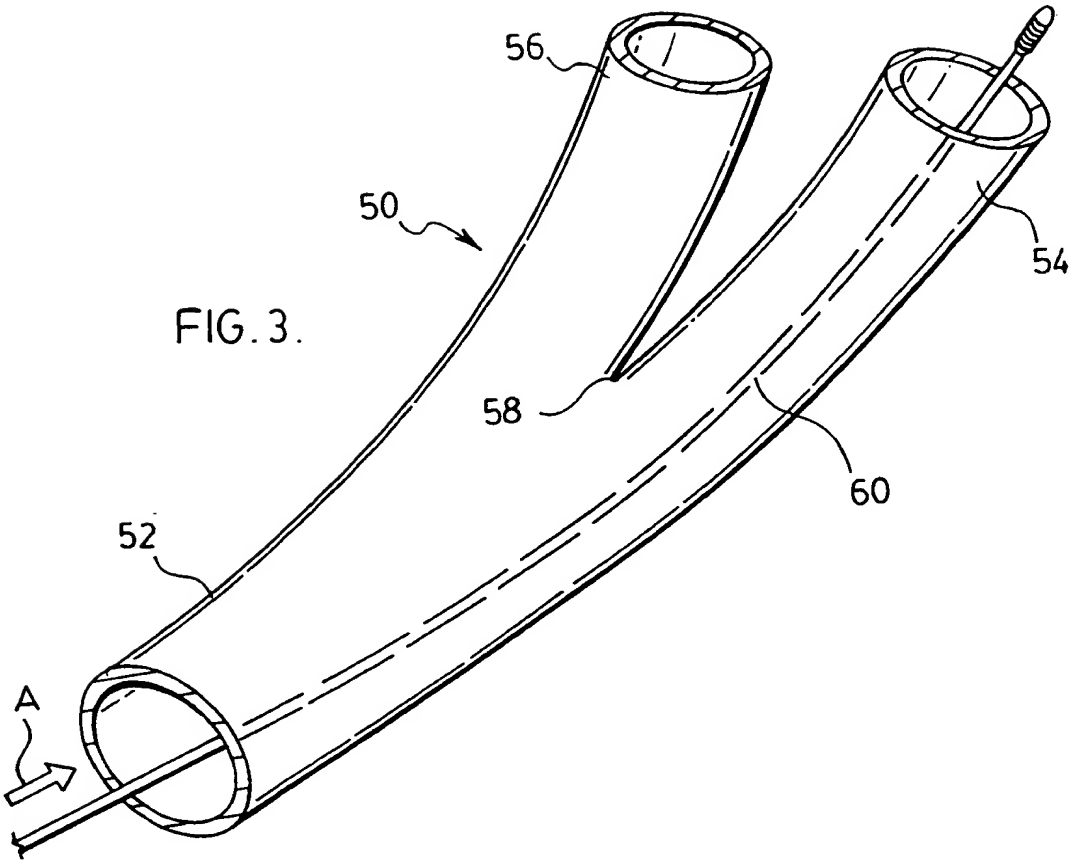

FIG. 3.

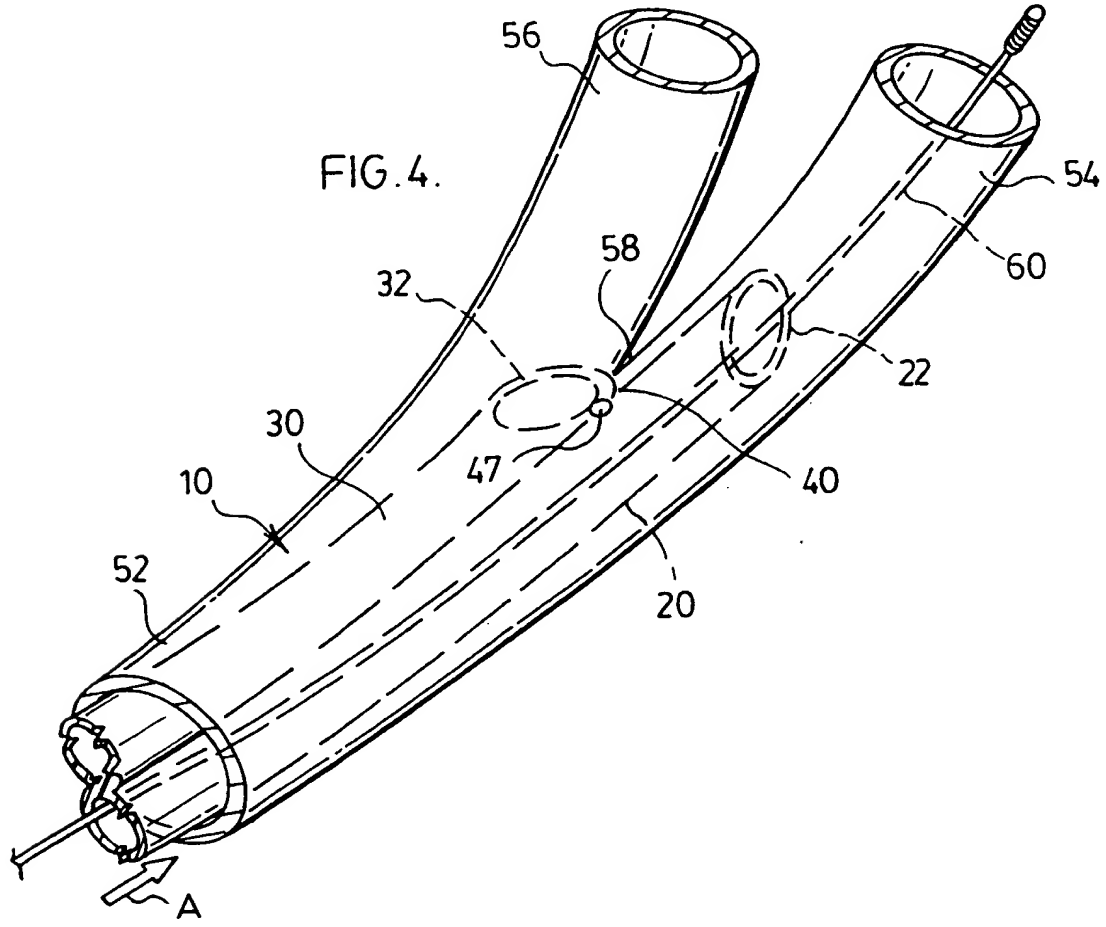

FIG. 4.

FIG.5.

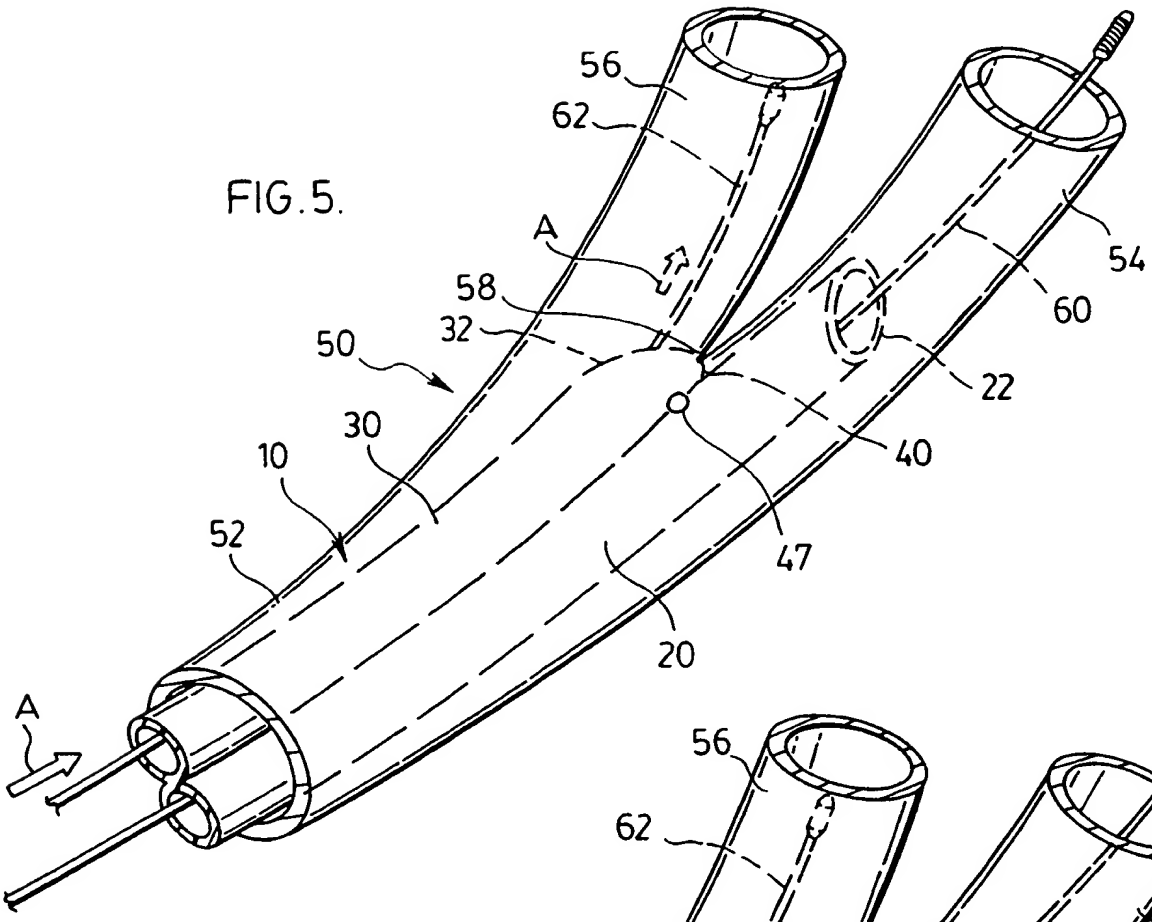
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FIG.6.

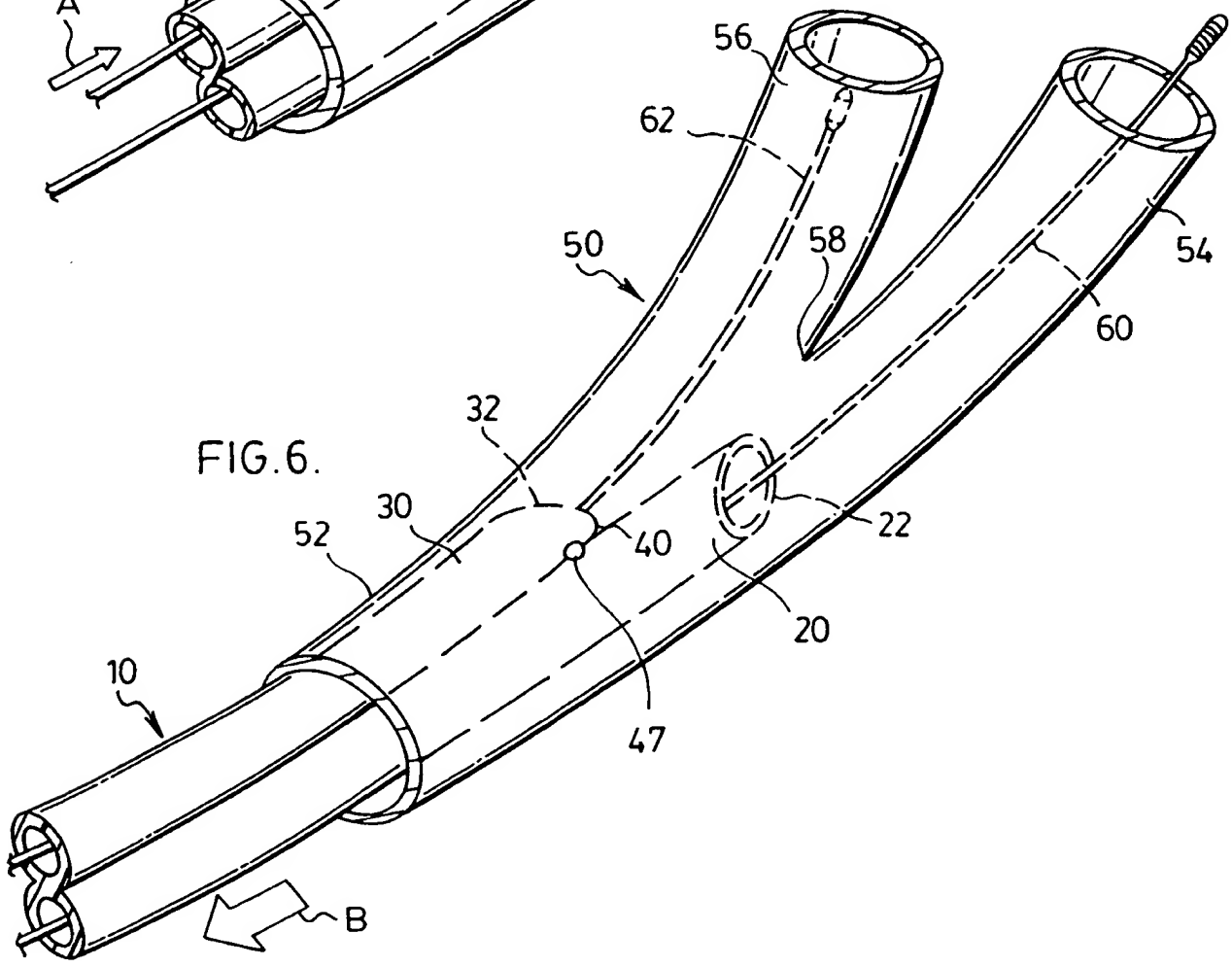
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FIG.7.

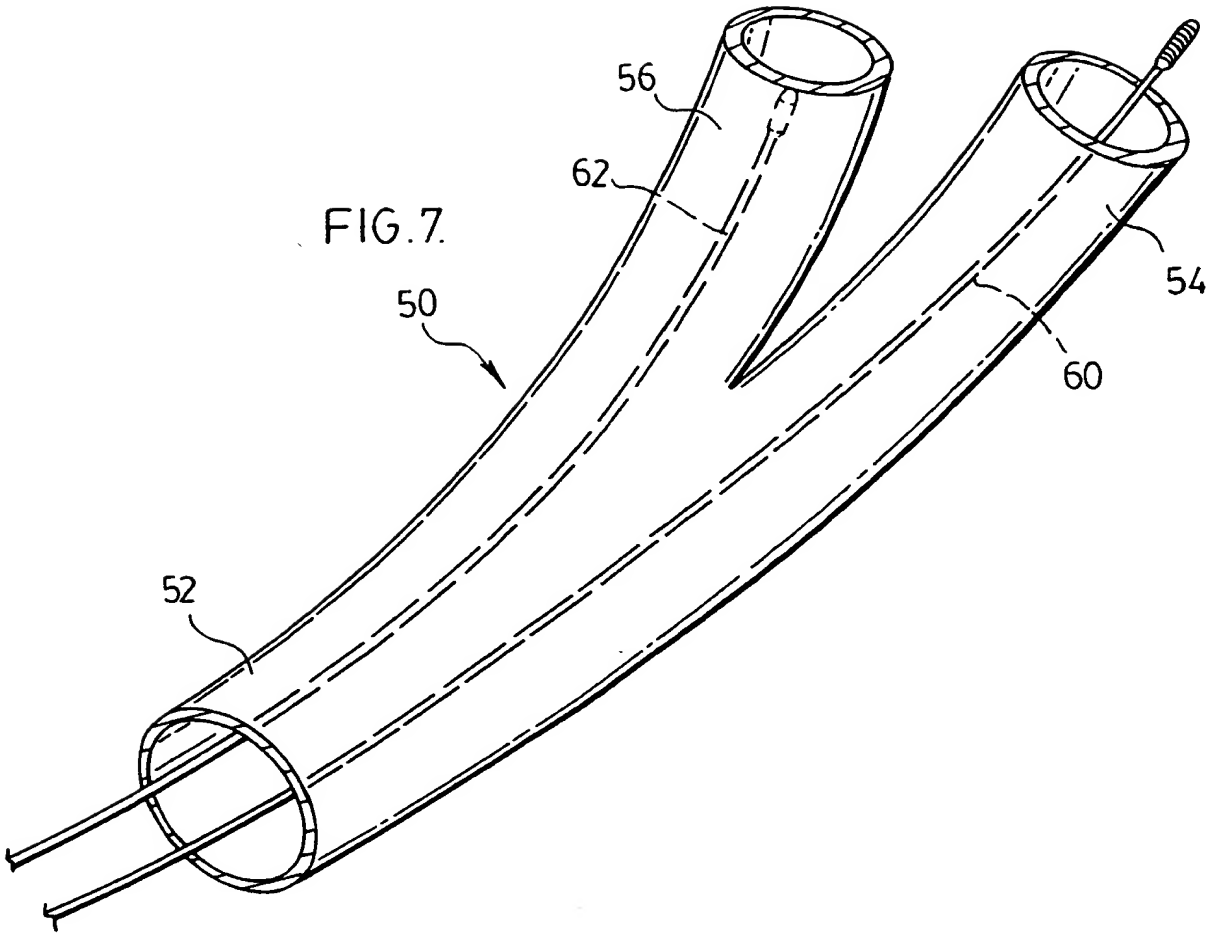


FIG.8.

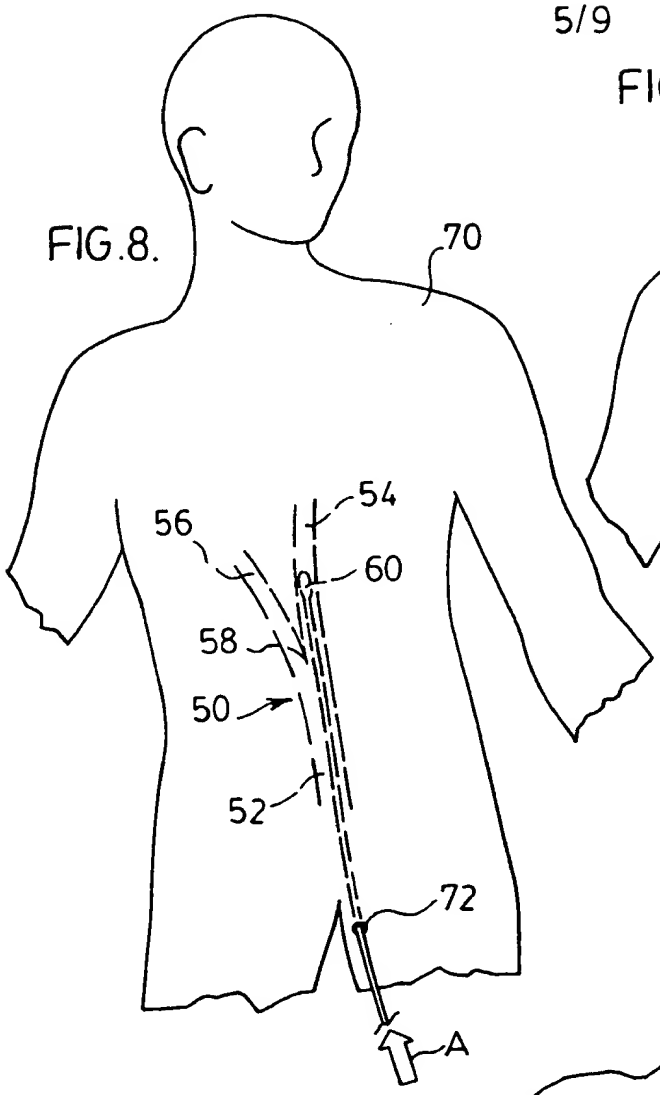


FIG.9.

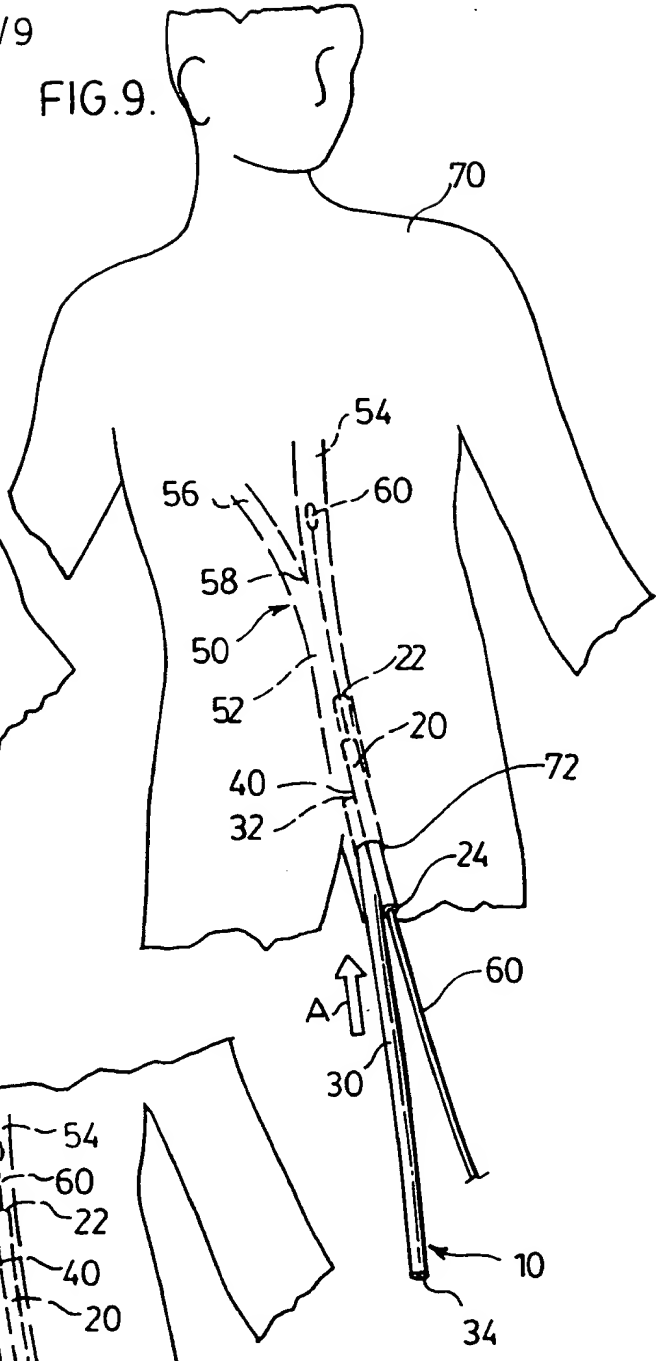
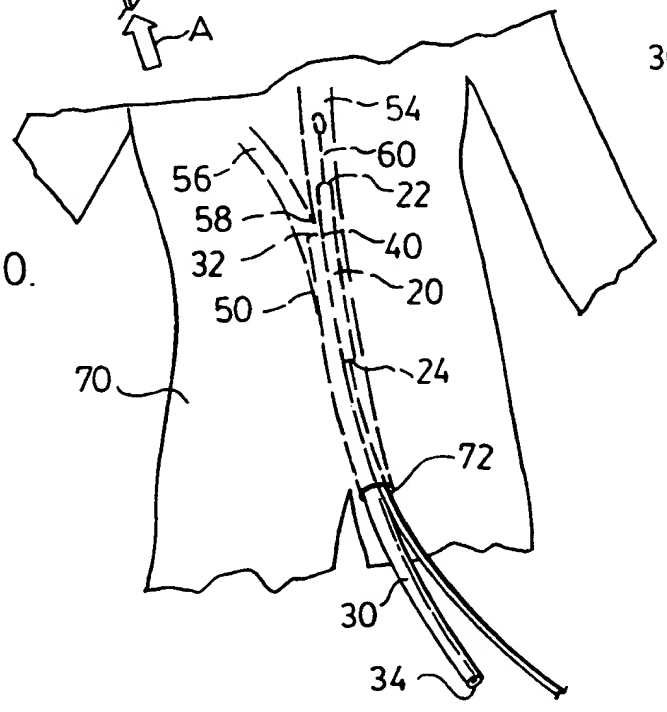


FIG.10.



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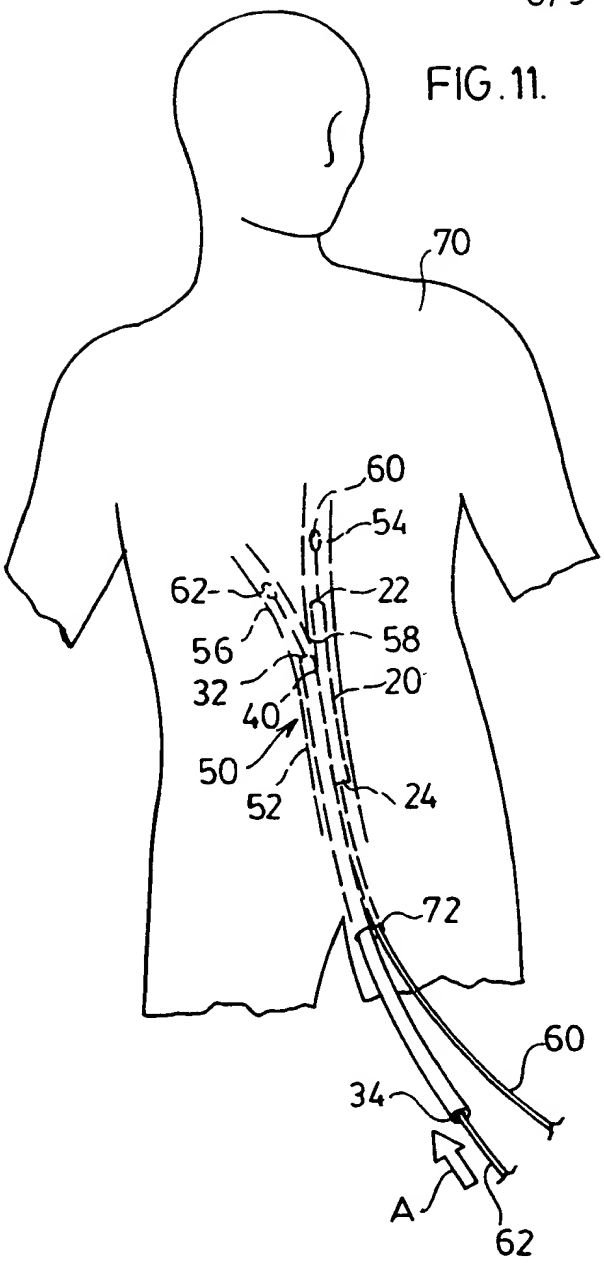
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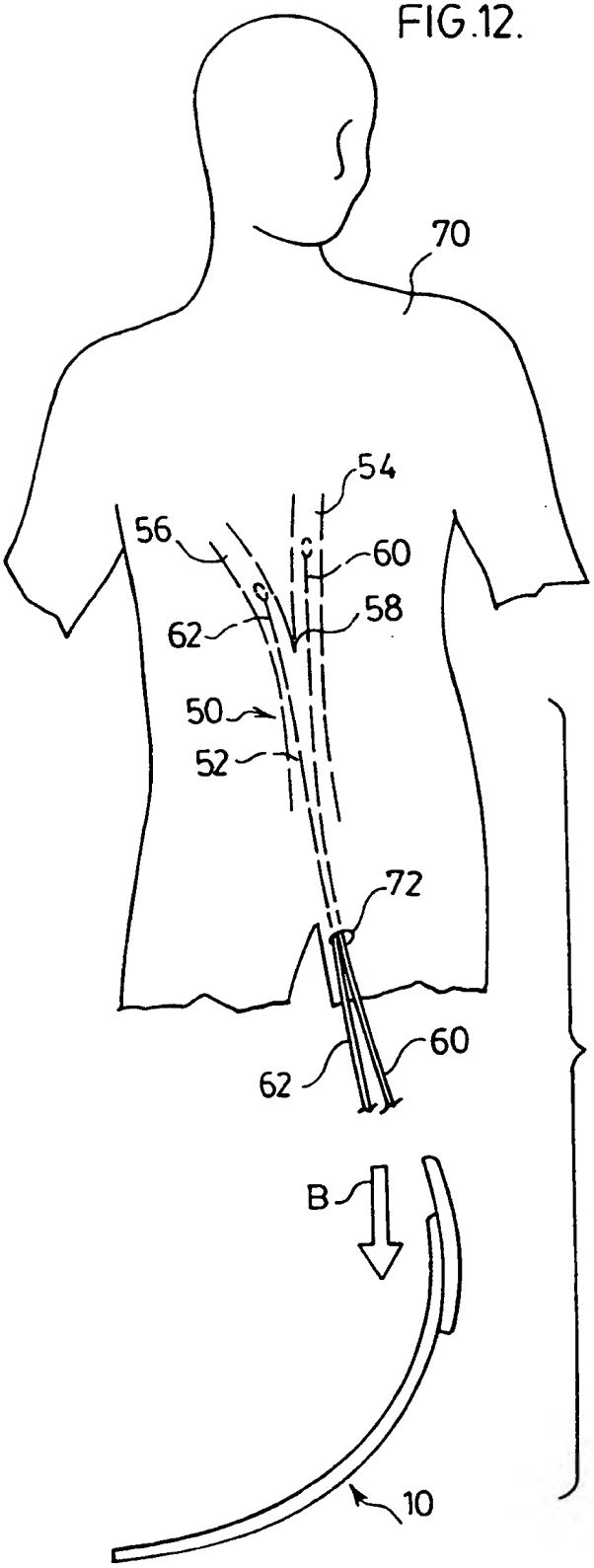
FIG.12.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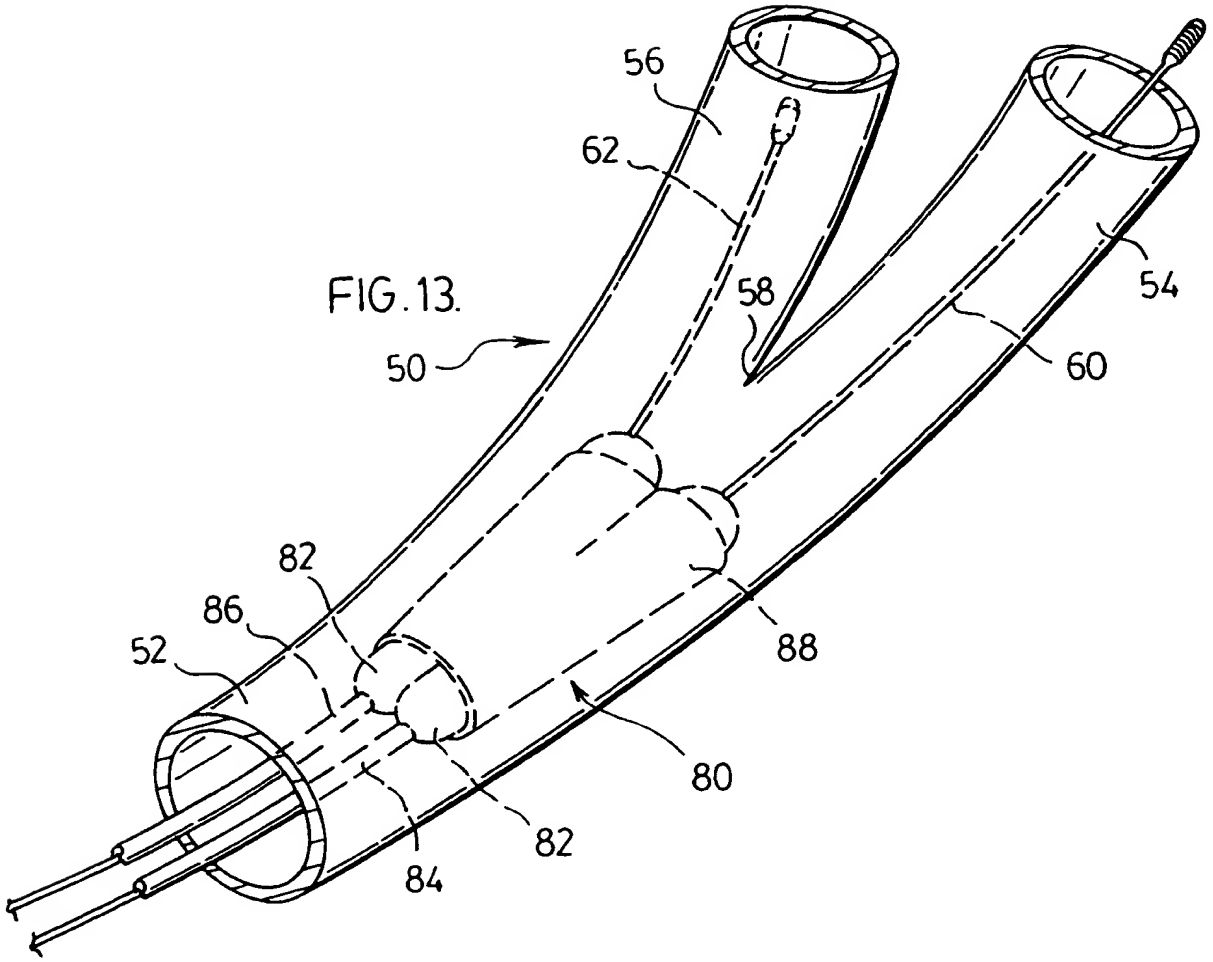

FIG. 13.

FIG. 14.

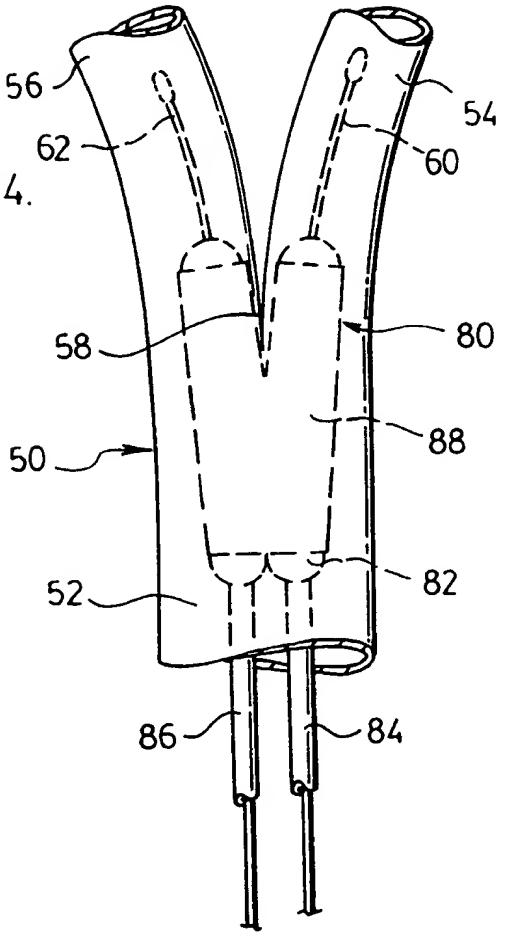

FIG. 15.

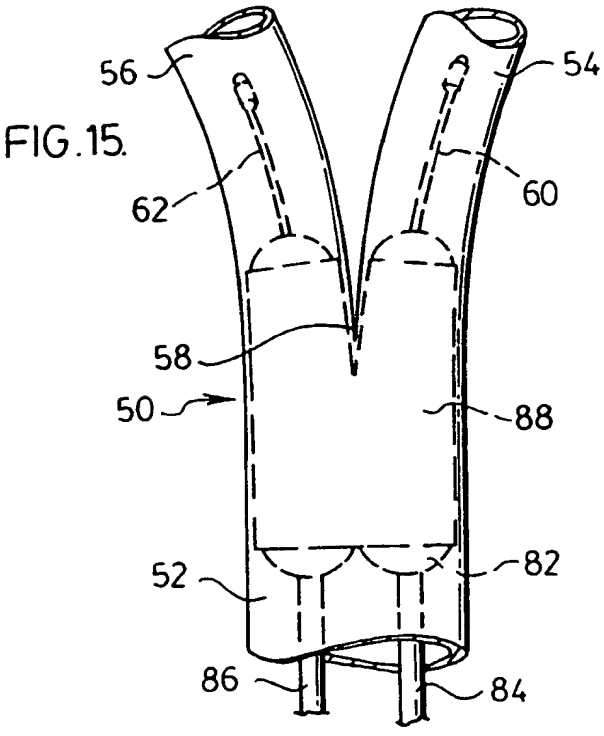

FIG.16.